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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/068,314
Filing Date: February 06, 2002
Appellant(s): TRESE ET AL.

Avery Goldstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/06/07 appealing from the Office action mailed 07/09/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the last paragraph, titled section C, is incorrect. The last office action only had two 103 Rejections, not three.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Trese et al. "Plasmin enzyme-assisted vitrectomy in traumatic pediatric macular holes" Ophthalmology, vol 105, issue 9 (Sep 1, 1998), pp.1617-1620

Trese et al. "A New Approach to Stage 3 Macular Holes" Ophthalmology 2000; 107: pp. 1607-1611.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7, 9, 10, 13-18, 20, 21, and 24 are under 35 U.S.C. 103(a) as being unpatentable over by Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye. Trese et al. discloses using 0.4 IU, but fails to disclose a size of dose smaller then 0.4 IU.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Trese et al. because it is well known in the medical field art to vary the does size that will be injected into a patient, since medication usually depends on the size of the patient as well as the area in which the injection will occur. This concept is well known in the research art and can be seen in the previous cited prior art (Entire reference). There is also a lack of criticality in the range claimed; therefore it would only take routine skill in the art to modify the dose of a medication through routine experimentation.

Claims 8, 19, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages

1617-1620) as applied to the claims above, and further in view of Trese et al. "A New Approach to Stage 3 Macular Holes" Ophthalmology 2000; 107: pp. 1607-1611[Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610)].

Trese et al. (Ophthalmology) discloses the claimed invention but fails to specifically point out the use of a plasmin inhibitor and the actual size of the needle being used to remove the liquefaction that occurred in the eye.

Trese et al. (American Academy of Ophthalmology) discloses the use of a plasmin for the liquefaction of the eye as well as the use of small gauge needles for sucking the material out of the eye (page 1610 2nd Column, 1st paragraph) and the use of a plasmin inhibitor to reduce to the activity of the plasmin that was injection into the eye (surgical techniques).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Trese et al. with Trese et al. because Trese et al. (American) provides further explanation as to why those steps are necessary. Trese et al. (American) also discloses the level of skill in the medical art since it is well known in the art to perform these steps. Trese et al. (America) provides motivation to use a small gauge so that there will be a smaller hole in the eye from the needle, and the plasmin inhibitor was used to control the amount of time and effectiveness of plasmin.

(10) Response to Argument

In the appeal brief the applicant is arguing several of the points that have been made throughout prosecution. The reasons the examiner has made the 103 Rejections is based on the fact that the first set of claims dated 02/06/02 had the dose of a plasmin

composition between 0.01 and 5.0 units of plasmin and then further limits that range to 0.1 and 2.0 units of plasmin. The applicant never claims the range of less then 0.4 units of plasmin until the prior art (Trese et al. (Ophthalmology)) was given and then at that time the applicant amended to get around the reference and use language of less than 0.4 units since the reference taught 0.4 units. Therefore the examiner made a 103 Rejection since the ranged claimed lacked criticality. The applicant then argued criticality because of page 5, line 5 in the specification which discloses "in a pediatric patient where the volume of the eye is significantly smaller, a dose of 0.4 units **may** result in facilitating posterior vitreous detachment" but the examiner is not convinced that one of ordinary skill in the art wouldn't find it obvious to use that dose or use routine experimentation to find an appropriate dose for treating the patient. In the specification on page 5, line 5, the applicant never states that this is a critical dose or even an optimal dose; instead the specification states that you can adjust the dose to 0.4 depending on the size of the patient. Therefore the examiner still believes that the applicant has failed to show that **less than** 0.4 units of plasmin is a critical dose, because the line in the specification states 0.4 units not less then, as well as never states that sized dose will cause liquefaction. Applicant further mentions in page 7 of the remarks section dated 04/17/07 that that the physician or a person that is treating the patient modifies the dose depending on the circumstance and condition of the patient, therefore further supporting the examiner's assertion that in the medical field when treating patients several factors are used to decide the dose of a medicament and therefore causing the physician or a person treating the patient to vary or use

experimentation to find the correct dose. This line of reasoning is further supported by the recent Supreme Court case of KSR, which supported the concept of "obvious to try" which would help support the examiner's rejection.

The applicant argues that the dose of 0.4 in both prior art references fail to teach liquefaction, which the examiner disagrees with. Both prior art references teach a plasmin injected into the eye and then incubated, which is the exact same method claimed by the applicant. The only difference is the dose size. The fact that both references teach a plasmin injected into the eye and then incubated would cause some form of liquefaction. The examiner agrees that prior art reference never disclose complete liquefaction of the vitreous of the eye, but both references disclose some type of liquefaction.

The applicant further argues several points previously presented such as no reasonable expectation of success, and impermissible hindsight. The examiner still disagrees with the applicant (see remarks section in office actions dated 7/9/07; 1/18/07, 8/08/06 and 12/01/05) because the prior art teaches the same plasmin, the same incubation time and if you changed the dose the same dose, thus having the same claimed invention, thus having a reasonable expectation of success. The fact of the matter lies within the obviousness to change a range and change a dose from 0.4 to less then 0.4 and from the KSR case, the MPEP, the prior art and the level of skill in the art the examiner thinks it would be obvious and maintains his rejection.

With regards to the Declarations of record the examiner stated why he is wasn't convinced in the remarks section of the final rejection dated 07/30/03. The main issue the examiner had was that declarations were calling the plasmin in the prior art a different name such as a streptokinase-plasmin, and therefore the streptokinase-plasmin doesn't work as well as a plasmin, but this is not convincing because one of ordinary skill in would read the reference and see that the authors were calling the enzyme a plasmin and have no way of knowing a they should have used the term streptokinase-plasmin. The issue is not with the fact that the authors of the prior art of record were using streptokinase-plasmin, but instead it is with the fact that if a person picked up the prior art they would read the reference with the understanding that a plasmin was used, but streptokinase-plasmin since there is no mention of streptokinase-plasmin in the reference.

The declaration also failed to show any criticality to the dose of **less than** 0.4 units other than the couple of lines in the specification that state a dose of 0.4 units **may** result in facilitating posterior vitreous detachment. The specification doesn't even state the using of a does of less than 0.4 units as an appropriate size that will cause liquefaction. The specification states 0.4 and fails to state that this dose size will cause liquefaction, and the declarations don't solve this problem.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Matthew DeSanto

Art Unit 3763

December 21, 2007

Conferees:

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